

Application Number: 10/565,279

Amendment dated: March 2, 2009

Reply to Office Action of: 2 February 2009

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

—1. (currently amended) An adaptive feed-back controlled cardiac resynchronisation therapy system capable of dynamic AV delay and VV interval pacing related to changes in the data received from at least one hemodynamic sensor continuously monitoring a hemodynamic performance, said system comprising:

- a learning neural network module<sub>1</sub> for receiving and processing information of said at least one sensor and for learning at least one aspect of said hemodynamic performance ~~physiological aspect of said body;~~
- a deterministic algorithmic module<sub>1</sub> receiving parameters of said resynchronisation therapy from said neural network module ~~and for controlling said learning module,~~ and
- a therapeutic delivery means<sub>1</sub> for delivering said resynchronisation therapy, said therapeutic delivery means is connected to said deterministic algorithmic module and operated by it;

wherein in a non-adaptive operation mode of said system, said deterministic algorithmic module is used for implementing a supervised

learning scheme of said learning neural network module, and wherein said resynchronisation therapy is delivered according to parameters pre-programmed into said deterministic algorithmic module; and  
wherein in an adaptive operation mode of said system, said learning neural network module is used for dynamically changing the parameters of said resynchronisation therapy according to the information received from said at least one hemodynamic sensor, and wherein said resynchronisation therapy is delivered according to the parameters provided by said learning neural network module.

2. (original) A system according to claim 1 wherein said modules and therapeutic delivery means are implanted, delivering biventricular pacing with adaptive AV delay and VV interval, modified continuously with correlation to the hemodynamic performance of the heart.
3. (original) A system according to claim 1 wherein said neural network module employs a spiking neuron network architecture.

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4. (original) A system according to claim 1 wherein said neural network module employs a spiking neuron network architecture implemented as a silicon processor operating with extremely low clock frequency.
5. (original) A system according to claim 1 wherein said neural networks module is external.
6. (original) A system according to claim 1 wherein said at least one sensor is a non invasive sensor.
7. (original) A system according to claim 1 wherein said therapeutic delivery system is connected to said learning neural network module via a wireless communications link.
8. (original) A system according to claim 1 wherein said therapeutic delivery means is at least one selected from the group consisting of a biventricular pacemaker and a defibrillator, a biventricular pacemaker and a CRT-D device or any combination thereof.

9.     (original) A method for regulating a controlled delivery of a physiologically active agent to a patient comprising the steps of:
- obtaining continuous signal from at least one sensor monitoring physiological parameter of said patient;
  - processing said continuous signal by an algorithmic processing module and a learning module, and wherein said learning modules carries out adaptive learning in connection with said at least one sensor is first supervised by applying an accepted set of parameters, and
  - delivering a physiological signal by a delivery module in response to said processed signal, wherein said regulation either relates to said algorithmic process or to said learning process.
10.    (currently amended) A method for adaptive biventricular pacing control in ~~claim 9~~ comprising the steps of:
- performing the steps 1 to 3 as set forth in claim 9;
  - programming initial AV (atrioventricular) delay parameter and VV (interventricular delay) interval parameter of an algorithmic module;

- providing pacing in a non-adaptive CRT mode wherein an algorithmic deterministic module controls the delivery of pulses, and wherein pacing is provided according to said parameters,
- switching to an adaptive CRT mode wherein said AV delay and VV interval change dynamically in order to achieve optimal hemodynamic performance, and wherein said adaptive mode is limited to perform above a low limit of hemodynamic performance, and
- switching back to the non adaptive CRT mode whenever the hemodynamic performance is below a low limit of hemodynamic performance or a sensor failure or any other system failure is detected.

11. (currently amended) A method for adaptive dual chamber control ~~as in claim 9, wherein said delivery module is any selected from the group consisting of dual chamber pacemaker and dual chamber defibrillator (ICD), further~~ comprising the steps of:

- performing the steps 1 to 3 as set forth in claim 9; wherein said delivery module is any selected from the group consisting of: a dual chamber pacemaker and dual chamber defibrillator (ICD);

- programming initial AV (atrioventricular) delay parameter of an algorithmic module;
- operating in non-adaptive mode wherein an algorithmic deterministic module for controlling delivery of pulses, wherein pacing is carried out according to said parameter and wherein learning operation with said parameters takes place;
- switching to adaptive mode whereby said AV delay changes dynamically in order to achieve optimal hemodynamic performance, and wherein said adaptive mode is limited to perform above a predefined low limit of hemodynamic performance, and
- switching back to non adaptive mode whenever the hemodynamic performance is lower ~~that~~ than a low limit of hemodynamic performance or a sensor fails or any other system failure is detected.

12. (currently amended) A method for adaptive biventricular pacing control as in claim 10 ~~and~~ or a method for adaptive dual chamber pacing control as in claim 11, wherein said sensor information relates to at least one sensor selected from the group consisting of: a ventricular pressure sensor, a ventricular blood impedance sensor, a ventricular wall motion accelerometer sensor and a QT interval sensor.

13. (currently amended) A method for regulating a controlled delivery of a physiologically active agent as in claims 9 ~~to~~ or a method for adaptive biventricular pacing control as in claim 10 or a method for adaptive dual chamber pacing control as in claim 11, wherein said learning module is a neural network module.
14. (currently amended)—A method for regulating a controlled delivery of a physiologically active agent as in claim 9 or a method for adaptive biventricular pacing control as in claim 10 or a method for adaptive dual chamber pacing control as in claim 11, ~~claims 9 to 11~~ wherein said ~~a~~ synaptic weight learning rule is Hebbian.
15. (currently amended) A method for regulating a controlled delivery of a physiologically active agent as in claim 9 or a method for adaptive biventricular pacing control as in claim 10 or a method for adaptive dual chamber pacing control as in claim 11, ~~according to Claims 9 to 11~~ wherein said learning module is a neural network module; wherein said neural network module employs a spiking neuron network architecture implemented as a silicon processor operating with extremely low clock frequency and hence dissipate extremely low battery power.

16. (currently amended) A method for adaptive biventricular pacing control as in ~~claims 12 and 13~~, used for ventricular pacing beyond the maximal tracking rate (MTR) limit, wherein the neural network processor is trained to predict the atrial event timing relative to the preceding ventricular event using the hemodynamic sensor signal that reflects ventricular contraction and where the predicted atrial event replace the sensed atrial event when the MTR limit is reached.
17. (currently amended) A method for adaptive biventricular pacing control and a rate responsive atrial pacing as in claims 12, ~~and 13~~ wherein said patients are bradycardia patients, and, wherein the neural network processor predicts the optimal atrial event timing relative to the preceding ventricular event using the hemodynamic sensor signal that reflects ventricular contraction and where a stroke volume is optimized.
18. (currently amended) A method for adaptive biventricular pacing control and for ventricular capture management as in claims 12 ~~and 13~~, wherein the changes in the evoked response timing are correlated with the variation in pacing intervals timings and hence a capture is verified reliably and an

intrinsic ventricular beat can be discriminated from a ventricular evoked response.

19. (original) A method for a controlled delivery of a physiologically active agent as in claim 9 wherein said physiologic parameter is a glucose level and a physiologically signal delivered is insulin for delivering therapy to patients with diabetes.
20. (original) A method for a controlled delivery of a physiologically active agent as in claim 9 wherein said active agent is a brain stimulating device for delivering therapy to patients with a Parkinson disease.
21. (new) A method for adaptive biventricular pacing control and a rate responsive atrial pacing as in claim 13, wherein said patients are bradycardia patients, and wherein the neural network processor predicts the optimal atrial event timing relative to the preceding ventricular event using the hemodynamic sensor signal that reflects ventricular contraction and where a stroke volume is optimized.
22. (new) A method for adaptive biventricular pacing control and for ventricular capture management as in claim 13, wherein the changes in the evoked response timing are correlated with the variation in pacing intervals timings

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and hence a capture is verified reliably and an intrinsic ventricular beat can be discriminated from a ventricular evoked response.

23. (new) A method for adaptive biventricular pacing control as in claim 13, used for ventricular pacing beyond the maximal tracking rate (MTR) limit, wherein the neural network processor is trained to predict the atrial event timing relative to the preceding ventricular event using the hemodynamic sensor signal that reflects ventricular contraction and where the predicted atrial event replace the sensed atrial event when the MTR limit is reached.